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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/723,594	11/26/2003	Yuan-Ping Pang	07039-161002	7578

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FISH & RICHARDSON P.C.
PO BOX 1022
MINNEAPOLIS, MN 55440-1022

EXAMINER

NEGIN, RUSSELL SCOTT

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 04/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/723,594	Applicant(s) PANG, YUAN-PING	
	Examiner Russell S. Negin	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 February 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-72 is/are pending in the application.
- 4a) Of the above claim(s) 1-36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 37-72 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>3/19/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election of Group II in the reply filed on February 2, 2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-36 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Group, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on February 2, 2006.

The species election requirements pertaining to Group II are withdrawn, non-elected species are rejoined with elected species, and Group II is examined in its entirety.

Information Disclosure Statement

The Information Disclosure Statement filed March 19, 2004 does not contain a legible copy of each reference listed on the list of references. It is not known whether this is an error of the applicants or a scanning error by the Office. Consequently the missing references have been listed as not considered in the signed copy of the list of references attached to this Office action. If the applicants provide a legible copy of the missing references in response to this Office action, the references will be considered under 37 CFR 1.97(f), and a signed copy of the list of references indicating

consideration of the missing references will be provided to the applicants without the necessity of the applicants filing a second Information Disclosure Statement.

Documents AE through AS are missing as well as AU through ACC and AEE through All. They are not present in this or any parent application.

Specification

The disclosure is objected to because of the following informalities:

The abstract uses the abbreviation "MD" without stating that it is indicative of molecular dynamics.

Lines 7 and 8 of the abstract have two sentence fragments which need to be joined. Specifically, the statements, "A metal ion can have." and "The center atom covalently linked to one or more dummy atoms..." are fragments which need to be rejoined.

Line 9 on page 4 has a grammatical error in that the phrase, "It may a charge of about ..." needs a verb.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 37-72 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a metal ion composed of a single atom, does not reasonably provide enablement for a polyatomic metal ion. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

In *In re Wands* (8 USPQ2d 1400 (CAFC 1988)) the CAFC considered the issue of enablement in molecular biology. The CAFC summarized eight factors to be considered in a determination of "undue experimentation." These factors include: (a) the quantity of experimentation necessary; (b) the amount of direction or guidance presented; (c) the presence or absence of working examples; (d) the nature of the invention; (e) the state of the prior art; (f) the relative skill of those in the art; (g) the predictability of the art; and (h) the breadth of the claims.

The factors can be addressed as follows:

- a) While it is straightforward to make this invention for single atomic ions, there is undue experimentation required for polyatomic metal ions. An example of such a polyatomic metal ion is holo- bovine lactalbumin as described in Chrysina et al. [The Journal of Biological Chemistry, 2000, pages 37021-37029]. For example, there would be undue experimentation required to define the "center atom" of a polyatomic metal ion.
- b) There is no guidance presented in the specification of using polyatomic ions such as metalloproteins in the molecular modeling.

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- c) There are no working examples presented in the specification of using polyatomic ions such as metalloproteins in the molecular modeling.
- d) The nature of the invention is modeling metal ions for molecular dynamics simulations.
- e) The state of the prior art does not show how to model such polyatomic metal ions using the means claimed in the disclosure. The state of the prior art uses single atom metal ions bound to dummy atoms in order to represent certain moieties to which the metal ion is bound. For example, Haeffner et al. [Journal of Molecular Structure (Theochem), volume 297, 1997, pages 39-50] undergo such a study in their "Force field parameterization of copper(I)-olefin systems from density functional calculations." Haeffner et al. investigate the binding of copper ions to dummy atoms mimicking olefins to optimize parameters of a force field. In addition, the metal ion itself is not modeled according to the instant application; it is a charged sphere attached to an uncharged dummy atom.
- f) The skill in the art required to operate this invention is an advanced degree in biotechnology.
- g) It is unpredictable as to how one would conduct this invention on such a polyatomic metal ion described in Chrysina et al. It is unpredictable as to where the center ion would be located and where the dummy atoms would be positioned.
- h) The claim is broad enough to cover both monoatomic and polyatomic metal ions.

The skilled practitioner would first turn to the instant description for guidance in using the claimed invention. However, the description lacks clear evidence that enables

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execution of the invention for polyatomic metal ions. As such, the skilled practitioner would turn to the prior art for such guidance, however the prior art does not discuss the present model for the purposes of modeling polyatomic metal ions. Finally, said practitioner would turn to trial and error experimentation to determine said model for polyatomic metal ions. Such amounts to undue experimentation.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 37-72 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The independent claims 37 and 55 recite the limitation "one or more dummy atoms" but then later in the claim recite the same subject of dummy atoms in the plural, "said metal ion is evenly distributed among said dummy atoms." It is unclear as to the metes and bounds to claims 37 and 55, in that there is ambiguity in whether there are singular or plural dummy atoms in the model.

Claims 52, 53, 70 and 71 are indefinite because they list values of charge without assigning a sign (negative or positive) to the value.

Conclusion

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the central PTO Fax Center. The faxing of such pages must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61

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(November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)).
The Central PTO Fax Center Number is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Negin, Ph.D., whose telephone number is (571) 272-1083. The examiner can normally be reached on Monday-Friday from 7am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor, Ardin Marschel, Ph.D., Supervisory Patent Examiner, can be reached at (571) 272-0718.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (571) 272-0549.

Information regarding the status of the application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information on the PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

-RSN 4/16/2006

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John S. Brusca 16 April 2006
JOHN S. BRUSCA, PH.D.
PRIMARY EXAMINER